PATENT
Attorney Docket No.: 10139 - 04602

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Hehli et al.	)	
	)	
Serial No.: 10/694,846	)	Group Art Unit: 3733
	)	
Filed: October 29, 2003	)	Examiner: Nicholas W. Woodall
	)	
For: OSTEOSYNTHETIC DEVICE	)	**Board of Patent Appeals and Interferences**
	)	
	)	

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

In response to the Examiner's Answer mailed on September 5, 2008 to the Appeal Brief filed July 1, 2008, and pursuant to 37 C.F.R. § 41.41, Appellants present this Reply Brief in the above-captioned application.

This is an appeal to the Board of Patent Appeals and Interferences from the Examiner's final rejection of claims 1 - 18 in the Final Office Action dated February 4, 2008. The appealed claims are set forth in the attached Claims Appendix.

1. Status of the Claims

Claims 1 - 18 stand rejected in the Final Office Action. The final rejection of claims 1 - 18 is being appealed.

2. Grounds of Rejection to be Reviewed on Appeal

I. Whether claims 1, 2, 7, 9, 13, 14 and 17 are unpatentable under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,626,613 to Schmieding (hereinafter "Schmieding").

II. Whether claims 8, 10 and 12 are unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

III. Whether claims 3 - 6, 11 and 15 - 16 are unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

IV. Whether claim 18 is unpatentable under 35 U.S.C. § 103(a) as obvious over Schmieding.

3. Argument

I. The Rejection of Claims 1, 2, 7, 9, 13, 14 and 17 Under 35 U.S.C. § 102(b) as Anticipated by Schmieding Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, claims 1, 2, 7, 9, 13, 14 and 17 stand rejected under 35 U.S.C. 102(b) as anticipated by Schmieding. (*See* 9/5/08 Examiner's Answer, p. 3, pp. 5 - 9). In support of the rejection, the Examiner asserts that the device of Schmieding is capable of being used as an intramedullary nail in a small bone of a larger organism or a large bone of a smaller organism. (*Id.*).

B. Schmieding does not Disclose an Intramedullary Nail

It is respectfully submitted that Schmieding does not teach an "intramedullary nail," as recited in claim 1. The term "intramedullary nail" is clearly recognized by those skilled in the art as defining a specific device having defined structural qualities -- i.e., the nail must be sized and shaped to conform to the medullary canal into which it will be inserted, the materials must be biocompatible and strong enough to absorb the stresses to which the bone will be exposed, etc. to stabilize the bone. Specifically, every item which can fit within the medullary canal is not an intramedullary nail. There are many nails which are clearly not intramedullary nails even though they might fit in the medullary canal. For example, although a penny nail or horseshoe nail may fit in a medullary canal, the structure of such nails renders them wholly unsuitable for the purpose of an intramedullary nail and there is no chance than anyone skilled in the art would understand the term in such a manner as to encompass such items. The understanding of this term among those skilled in the art clearly involves structural qualities which are possessed by certain items and not others. This term defines to those skilled in the art certain specific structural qualities without which, an item ceases to be an intramedullary nail – e.g., a level of strength sufficient to support the bone under the levels of stress to which it will be exposed, biocompatibilty, a shape generally conforming to a length of the medullary canal into which it will be inserted, etc.

It is respectfully submitted that the Examiner's assertion that the device of Bono is "capable of fitting within the medullary canal of a bone," ignores this entirely and improperly reads the term "intrameduallary nail" out of the claim. Although the term "intramedullary nail"

indicates the intended use of the item, it also requires the structures necessary to perform the functions of an item being used in this intended manner. It is respectfully submitted that the device of Schmieding is in no way either intended for or suitable for use in the intramedullary canal and clearly is unsuitable to perform the function of an intramedullary nai. Furthermore, it is submitted that this device does not have the required structural attributes to function as an intramedullary nail and thus does not meet the limitation of "intramedullary nail," recited in claim 1. Specifically, the corkscrew suture anchor of Schmieding is clearly designed only to secure soft cancellous bone and is designed only to prevent suture attached to the bone from being pulled out of the bone. To presume such a suture anchor is in any way capable of functioning as an intramedullary nail is the height of speculation.

Still further, there is absolutely nothing in Schmieding that indicates that the suture anchor 2 is suitable for insertion into the medullary canal for any purpose whatsoever, much less to serve as an intramedullary nail. Rather, it would be clear to one of skill in the art that Bono actually teaches away from an "intramedullary nail," as recited in claim 1 since at least a portion of the suture anchor 2 must remain within the compact bone and extend to a position external to the bone in order to provide an anchor for soft tissue. (*See* Bono, col. 1, ll. 12 - 16, col. 4, ll. 16 - 22; Fig. 10). It is therefore respectfully submitted that Schmieding fails to read on the recited limitation of an "intramedullary nail."

Thus, it is respectfully submitted that the Examiner has not made a *prima facie* case of anticipation of independent claim 1, and that the rejection of claim 1, along with the rejections of dependent claims 2, 7, 9, 13, 14, and 17, should be withdrawn.

II. The Rejection of Claims 8, 10 and 12 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, claims 8, 10 and 12 were rejected under 35 U.S.C. 103(a) as unpatentable over Schmieding. ((*See* 9/5/08 Examiner's Answer, p. 4, pp. 5 - 9). The Examiner stated that Schmieding discloses the claimed invention except for the cross-section orthogonal to the central axis having a shape of a square, star, rectangle, or a rectangle with rounded edges but that this would be an obvious modification to the Schmieding device. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as recited in claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 8, 10 and 12 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is allowable over Schmieding. Accordingly, because claims 8, 10 and 12 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

As Schmieding's device is a suture anchor in no way suitable for use as an intramedullary nail, the Examiner's assertion that the claimed shapes which enhance the functioning of an intramedullary nail would be a mere design choice ignores the impact such a shape change might

have on the actual function of the suture anchors of Schmieding. This speculation by the Examiner is entirely unsupported by the cited reference and it is submitted that the suggested changes are at least as likely to impede the functioning of the suture anchors 2 as they are to enhance it. In any case, it is respectfully submitted that there is nothing in the cited art that shows or suggests any of these limitations. It is submitted that Schmeiding includes no description that would lead one of skill in the art to believe that such modifications would make the Schmieding device more suited for its purpose or for the purpose of the present invention and, therefore, that this reference provides absolutely no motivation for the proposed modification. Thus, it is submitted that the modifications proposed by the Examiner constitute an improper hindsight reconstructions of the invention and that this rejection should be withdrawn.

III. The Rejection of Claims 3 - 6, 11 and 15-16 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, claims 3 - 6, 11 and 15-16 were rejected under 35 U.S.C. 103(a) as obvious over Schmieding. (*See* 9/5/08 Examiner's Answer, pp. 4 - 9). The Examiner stated that Schmieding discloses the claimed invention except for the helix having a rotation of less than 540 degrees, the radius of the cylinder falling in the range of 10 - 50 mm., etc. but that it would have been obvious to have modified the Schmieding device to include these limitations. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claims 3 - 6, 11 and 15 - 16 depend from and therefore include all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable. Accordingly, because claims 3 - 6, 11 and 15 - 16 depend from and, therefore, include all of the limitations of independent claim 1, it is respectfully submitted that these claims are also allowable.

Furthermore, as discussed above, Schmieding's device is a suture anchor in no way suitable for use as an intramedullary nail and the Examiner's assertion that the rotation of less than 540 degrees which enhance the functioning of the claimed intramedullary nail would have been obvious to one skilled in the art in reviewing this suture anchor reference ignores the impact such a shape change would have on the actual function of these suture anchors. This speculation by the Examiner is entirely unsupported by the cited reference and it is submitted that the suggested changes are likely to impede the functioning of the suture anchors 2 by reducing the degree to which the anchors may be inserted into the bone. In any case, it is respectfully submitted that there is nothing in the cited art that shows or suggests any of these limitations. It is submitted that Schmeiding includes no description that would lead one of skill in the art to believe that such modifications would make the Schmieding device more suited for its purpose or for the purpose of the present invention and, therefore, that this reference provides absolutely no

motivation for the proposed modification. Thus, it is submitted that the modifications proposed by the Examiner constitute an improper hindsight reconstructions of the invention and that this rejection should be withdrawn.

IV. The Rejection of Claim 18 Under 35 U.S.C. § 103(a) as Obvious over Schmieding Should be Reversed

A. The Examiner's Rejection

In the Examiner's Answer, claim 18 was rejected under 35 U.S.C. 103(a) as obvious over Schmieding. (*See* 9/5/08 Examiner's Answer, p. 3, pp. 5 - 9). The Examiner stated that Schmieding discloses the claimed invention except for the device having at least two through holes but that it would have been obvious to have modified the Schmieding device to include this limitation. (*Id.*)

B. Schmieding Does Not Disclose an Intramedullary Nail as Recited in Claim 1

Claim 1 has been recited above and discussed with reference to the 35 U.S.C. § 102(b) rejection. Claim 18 depends from and therefore includes all the limitations of independent claim 1. As discussed above, Schmieding does not teach or suggest the limitations of independent claim 1 and claim 1 is therefore allowable over Schmieding. Accordingly, it is respectfully submitted that this claim is allowable for the same reasons stated in regard to claim 1.

4. Conclusion

For the reasons set forth above, Appellants respectfully request that the Board reverse the final rejections of the claims by the Examiner under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) and indicate that claims 1 - 18 are allowable.

Respectfully submitted,

Date: November 5, 2008

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CLAIMS APPENDIX

1. (Previously Presented) An osteosynthetic device comprising an intramedullary nail having a longitudinal shape with a central axis, a first end, and a second end, wherein the shape of the device is helical.

2. (Original) The osteosynthetic device of claim 1, wherein the envelope of the helix is a cylinder having the same central axis as the helix.

3. (Previously Presented) The osteosynthetic device of claim 1, wherein the helix has a rotation of less than 540°.

4. (Previously Presented) The osteosynthetic device of claim 1, wherein the radius of the cylinder is in the range of 10 to 50 mm.

5. (Previously Presented) The osteosynthetic device of claim 1, wherein the pitch of the helix is in the range of 100 to 1500 mm.

6. (Previously Presented) The osteosynthetic device of claim 1, wherein the pitch of the helix is greater than 400 mm.

7. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is a circle.

8. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is a square or a star.

9. (Original) The osteosynthetic device of claim 1, wherein the second end is pointed.

10. (Original) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis of the helix is essentially a rectangle with the sides a and b, the larger side b being oriented to the outer and inner sides of the helix.

11. (Previously Presented) The osteosynthetic device of claim 10, wherein the ratio of a:b is smaller than 0.5.

12. (Original) The osteosynthetic device of claim 10, wherein the essentially rectangular cross-section is rounded at its smaller sides a.

13. (Original) The osteosynthetic device of claim 1, wherein the portion of the helix near the first end is thicker than the portion of the helix near the second end.

14. (Original) The osteosynthetic device of claim 1, wherein the central axis of the helix is a straight line.

15. (Previously Presented) The osteosynthetic device of claim 1, wherein the cross-section orthogonal to the central axis has a maximum dimension in the range of 5 to 14 mm.

16. (Previously Presented) The osteosynthetic device of claim 1, wherein the length of the cylinder or of the helix is in the range of 200 to 500 mm.

17. (Original) The osteosynthetic device of claim 1, wherein the device is provided with through holes for locking screws, preferably near the second end.

18. (Previously Presented) The osteosynthetic device of claim 1, wherein the device is provided with at least two through holes for locking screws.